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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,852	05/16/2006	Pier Luigi Delvigo	PIER0101PUSA	7867

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EXAMINER	
WIEST, PHILIP R	
ART UNIT	PAPER NUMBER
3761	
MAIL DATE	DELIVERY MODE
11/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,852	DELVIGO, PIER LUIGI	
	Examiner	Art Unit	
	Philip R. Wiest	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *15 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-41* is/are pending in the application.

4a) Of the above claim(s) *36-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 7-35 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. In the reply filed 9/15/09, applicant amended claims 1, 4, 7, 10, and 16, and cancelled claim 6. Claims 1-5 and 7-41 are currently pending, and claims 36-40 are withdrawn.

Response to Arguments

2. Applicant's arguments filed 9/15/09 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly considered prior art.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 1, 6-13, and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fredeking (US 4,678,458). Fredeking teaches a safety apparatus for transfusing blood contained within a bag 41 having an elastically deformable tube comprising a constriction device 51 closed by clamping means 65 that is moveable about the tube 36 so as to prevent blood from flowing through the tube. The

constriction device comprises a plurality of coding elements encoded thereon, thereby forming a locking mechanism (i.e. seat) into which a key is inserted (see Figures 1-4). The series of coding elements (i.e. projecting teeth) substantially prevent the constriction device from being unlocked until a specific corresponding key is inserted, the key having corresponding coding elements that line up with those of the locking device. Fredeking teaches that each patient is assigned a unique key, such that the key can only be used to unlock that specific patient's flow path (Column 2, Lines 4-19). Once a patient has blood removed and centrifuged, the key is removed from the constriction device and assigned to the patient, thereby closing the constriction device. The device cannot be reopened to establish blood flow until the key is returned to the locking mechanism. Further, once the key is reinserted into the locking mechanism to establish flow, it is fully capable of being irreversibly held by the locking mechanism -- either by moving the swing arm into the closed position (column 3, Lines 45-50) or by applying a tie 79 to the lock (Column 3, Lines 51-55 and Figure 3).

Fredeking teaches the device substantially as claimed, but does not specifically teach that the key is a circular disk.

Fredeking does not teach any structural elements corresponding to a circular key and constriction device. However, mere changes in shape do not constitute patentable improvements in the art when said changes do not provide functional improvements over the prior art. In this case, Fredeking provides a locking tube clamp for preventing blood transfusions to incorrect patients. Fredeking's device clamps around the tube, thereby preventing blood flow through the tube until a user-specific key is inserted.

Fredeking's device therefore performs the same function as the instant device, and the mere rearrangement of parts/change of shape such that the key and constriction device are circular does not provide a patentable improvement over the prior art (see MPEP § 2144.04). Therefore, it would have been merely an obvious engineering choice to one of ordinary skill in the art to rearrange the blood flow constriction device and key of Fredeking in a circular manner, because doing so does not provide any additional functionality over the prior art.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fredeking in view of MacNeill (US 4,346,869). Fredeking reasonably suggests the device substantially as claimed, but does not specifically teach or suggest that the clamp comprises a series of transverse ribs. MacNeill teaches a tube clamp having a plurality of transverse ribs that engage the outer walls of the tube (see Figure 4). The ribs are spaced such that upper rib 32 is received between lower ribs 42, thereby allowing the tube to be completely closed between the ribs. Additionally, because the ribs are curved, the clamp is substantially prevented from damaging or puncturing the tube during clamping. Tube clamps having a plurality of ribs are well known in the art for this reason. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the constriction device of Fredeking with MacNeill's ribbed tube clamp, thereby providing an improved means for completely closing the clamp without damaging or puncturing the flexible tube.

6. Claims 3, 5, and 20-35, rejected under 35 U.S.C. 103(a) as being unpatentable over Fredeking in view of Greenwalt et al. (US 4,685,314).

7. With respect to Claims 3, 5, and 20-35, Fredeking teaches the device substantially as claimed, and further suggests that each unique key is associated with a specific patient (Column 5, Lines 5-19). Fredeking, however, does not specifically teach that the key is housed in a *wristband* that is worn by the patient. Greenwalt teaches a device and method for preventing transfusion of incompatible blood comprising a blood bag having a locking means (1, 2) disposed thereon, such that the blood bag may only be accessed by unlocking it with a patient-specific key 3 (see Figures 1 and 2). Once a patient's blood type has been determined, a corresponding key is affixed to the patient, preferably by a wrist band, so as to ensure that only the correct blood type may be transfused (Column 8, Line 64 through Column 9, Line 25). Greenwalt, therefore, clearly suggest the need to keep the wristband with the patient, such that the keys from different patients are substantially prevented from being swapped. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the transfusion safety apparatus of Fredeking with Greenwalt's use of a wristband to store the key on the patient's body, because doing so provides a simple means of securing the key to the patient in a well known, comfortable manner.

Regarding the specific structural elements claimed, these elements are drawn to securely attaching a *circular* key to a wristband. As discussed above, it would have been an obvious matter of engineering choice to reconfigure the device of Fredeking so that the key and constriction device are circular because doing so does not substantially

change the function of the device as a whole. In addition, it would have been obvious to modify the key-holding wristband suggested by Fredeking and Greenwalt in order to be configured to receive a circular key, because *the specific claimed structural elements of the wristband are drawn to securely holding a circular key*. The mere rearrangement of parts of the wristband so as to securely hold a circular key does not constitute a patentable improvement in the art because the resulting device would have a substantially similar function to the prior art. See MPEP § 2144.04.

8. With respect to Claim 4, Fredeking and Greenwalt reasonably suggest the device substantially as claimed (see above), and Greenwalt further teaches that a variety of coding means (such as color coding) may be used to identify blood type. Greenwalt teaches that the key, the wristband, and the blood bag must all be labeled so as to provide *additional visible indication* of the blood type that is to be transfused. The key is to be placed in a wristband of the same color, and is only capable of unlocking a transfusion bag of the same color. Greenwalt, therefore, clearly teaches the use of labeling means to identify the transfusion bag, locking means, and patient wristband by blood type. It has been held printing matter used as coding means does not distinguish the claimed product from the prior art unless there is a new and non-obvious relationship between the printed matter and the substrate (see MPEP 2112.02 (III)). In this the use of coding means to visually identify equipment that is to be used with a certain blood type is well known in the art. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the transfusion safety device of

Fredeking with Greenwalt's coding system, such that the type of blood associated with each piece of transfusion equipment may be readily identified.

9. Claims 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fredeking in view of Delvigo (US 5,925,028). Fredeking teaches the device substantially as claimed, but does not specifically teach that the constriction device is irreversibly connected to the bag. Delvigo teaches a blood transfusion device wherein a flow control member (2, 3) is connected to a tubing system in order to establish fluid communication with the bag. The member 2 is connected to a strip 23 that keeps it permanently linked to the bag (see Figure 9). By doing this, the accidental loss or disengagement of the member 2 from the bag can be substantially prevented (Column 4, Lines 7-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the safety apparatus of Fredeking with the permanent attachment means of Delvigo, because doing so would substantially prevent the accidental misplacement of the flow clamp.

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fredeking in view of Greenwalt, and further in view of Delvigo. Fredeking and Greenwalt reasonably suggest a method of using the safety apparatus of Claim 1 comprising determining the blood type of the blood in a transfusion bag, labeling the bag according to the determined blood type (see the rejection of Claim 4), mounting a constriction device with the same information on the tube, identifying the blood group of

a patient, recording the patient's blood type in a hospital file and on a tab that is attached to a wristband that is to be fastened to said patient's wrist, labeling the wristband and fastening it to the patient's wrist (see the rejection of claims 3 and 5), selecting the number of blood bags to be transfused, and attaching the keys that correspond to said blood bags to said wristband. Once the operation is to be carried out, the key is retrieved from the patient, such that the constriction device may be opened. Using this system, the user is *fully capable* of providing each patient with an individual tag to be carried with them at all times and coded in a manner corresponding to the their blood type, such that the user may determine the patient's blood type in the event that the patient is admitted to the hospital. Fredeking and Greenwalt, however, do not specifically teach that the constriction device is permanently attached to the bag.

Delvigo teaches a blood transfusion device wherein a flow control member (2, 3) is connected to a tubing system in order to establish fluid communication with the bag. The member 2 is connected to a strip 23 that keeps it permanently linked to the bag (see Figure 9). By doing this, the accidental loss or disengagement of the member 2 from the bag can be substantially prevented (Column 4, Lines 7-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the safety apparatus of Fredeking and Greenwalt with the permanent attachment means of Delvigo, because doing so would substantially prevent the accidental misplacement of the flow clamp.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
20 November 2009